

REMARKS

The Office Action mailed on January 4, 2010, has been reviewed and the comments of the Examiner carefully considered. Applicants acknowledge the Examiner's withdrawal of all previously-pending rejections of the claims.

Claim 17 is amended herein, to incorporate the subject matter of claim 18. Claims 18, 21 and 22 are cancelled herein. Claims 9, 10, 17, 19 and 20 are currently pending and under consideration.

Rejection Under 35 U.S.C. § 103(a)

Claims 9, 10 and 17-22 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Tunc (U.S. Patent No. 3,800,797) in view of Komai (U.S. Patent No. 5,561,114) or Reich (U.S. Patent No. 5,124,155). The Examiner is of the view that this combination of references would motivate the skilled artisan to arrive at the claimed invention. Applicants respectfully disagree with the rejection for the following reasons.

As a preliminary matter, claims 18, 21 and 22 were cancelled, rendering the rejection of these claims moot. For the remaining claims, including amended claim 17, Applicants note that the claims are directed to compositions having, on each saccharide residue of the synthetic sulfated polysaccharide, from about 3 to about 4 sulfate groups that were converted from hydroxyl groups.

The test which must be met for a reference or a combination of references to establish obviousness has not been satisfied in the instant matter. The MPEP states, in relevant part, the proper test for obviousness:

Office policy is to follow *Graham v. John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C. § 103 ...

[T]he four factual inquiries enunciated therein as a background for determining obviousness are as follows:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations. (MPEP § 2141).

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When applying 35 U.S.C. § 103, the following tenets of patent law must be followed: 1) the claimed invention must be considered as a whole; 2) the references must be considered as a whole; 3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and 4) reasonable expectation of success is the standard with which obviousness is determined. MPEP § 2141 II.

As Applicants have noted previously, the rejection is based primarily on Tunc's teaching of barrier film (e.g., sodium hydroxyethyl cellulose sulfate) and Komai's disclosure that the sulfation degree is up to 1.5, and in some instances, up to 2.9. However, Applicants submit that the reading of the references, and of Komai in particular, is incorrect in view of the requirements of 35 U.S.C. § 103, described above.

Tunc teaches minimizing the degree of sulfation (e.g., see the bottom of column 3 and the top of column 4 of Tunc, which states “Specifically, by lowering the degree of sulfation, the barrier films of this invention become more resistant to salt solutions in that they retain their integrity after being subjected to these solutions for longer periods of time and that they exhibit higher tensile strengths when subjected to a given salt concentration for a given period of time. In general, if the D. S. is maintained, at below about 0.4 an adequately salt resistant film results. Preferably, the D. S. should be maintained at below about 0.3 and more preferably below 0.2.” Emphasis added).

The Komai reference is argued in the Office Action to “teach” degrees of sulfation up to 2.9. However, this is simply not accurate, if the Komai reference is properly read for all it teaches. As set forth previously, that single statement in Komai regarding a level of sulfation of 2.9 merely references the versatility of the methods used in Komai, and the entire remainder of the Komai reference emphasizes minimizing the degree of sulfation as a key aspect of the invention. For example, lines 31-55 of column 3 in Komai emphasizes and directs the skilled artisan to the incontrovertible conclusion that the invention of Komai does not operate with degrees of sulfation approaching 2.9. For example, the passage at lines 31-36 – which immediately follow a broad, general statement regarding a degree of sulfation of 2.9 – states: “Since highly sulfated species of the cellulose sulfate fiber obtainable by the above methods are water-soluble, they are not so suitable for the nonwoven fabric of the invention. The degree of substitution (DS) of cellulose sulfate fiber suitable for the nonwoven fabric of the invention is

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generally in the range of 0.01 to 1.5.” Komai goes on to explicitly state: “[W]ith a DS value over 0.2, the cellulose sulfate fiber swells remarkably in water and even partially dissolves in water so that it fails to retain its fibrous geometry and strength, thus being unsuited for purposes of the invention.”

Both references teach advantages of keeping the degree of sulfation at 0.2 or below. Accordingly, the skilled artisan would have no motivation whatsoever to combine the two references to arrive at Applicants’ present claims, which encompass a degree of sulfation from about 3 to about 4. Assuming, *arguendo*, that the skilled artisan had some reason to combine the Tunc and Komai references, the only motivation to combine the references would be for the teachings in both references of the advantages of keeping the degree of sulfation at 0.2 or below. Thus, even such motivation for a combination would not lead the skilled artisan to the present claims, which are directed to a degree of sulfation from about 3 to about 4.

The Office Action states that “One of ordinary skill in this art would be motivated to combine the teaching of the Tunc patent with the teaching of the Komai et al patent since both documents disclose using nonwoven cellulose sulfate with fibronectin material or in wounds. One of ordinary skill in this art would also be motivated to combine the teaching of the Tunc patent with the teaching of the Reich patent since both documents disclose preparation of wound dressings.” However, none of these conclusions address the elements of Applicants claims, and particularly the claims as presently amended. Therefore, none of these conclusions would provide any teaching or suggestion for the skilled artisan to arrive at the pending claims.

MPEP 2141 requires that “When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.” (Emphasis added). Applicants respectfully submit that the conclusions set forth in the Office Action do not meet this burden, because the necessary facts and understandings of one of skill in the art are not pointed out with any particularity. In other words, the Office Action does not

provide any reasoning to show a nexus between the references cited and the presently-pending claims.

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). See MPEP 2141.02. Applicants note that both Komai and Tunc teach away from the presently claimed invention, which encompasses a degree of sulfation from about 3 to about 4. The prior art references both teach and suggest a degree of sulfation at 0.2 or below. When each reference is read in its entirety, for all it fairly teaches, the skilled artisan could only find motivation to minimize the degree of sulfation, at a level greater than ten times lower than the levels presently claimed.

Furthermore, support for the range “about 3 to about 4” can be found throughout the specification. The skilled artisan is adequately apprised of the meaning of a degree of sulfation of “about 3”, for example. There is abundant direction in the specification as to how the skilled artisan would measure the extent of sulfation of any given molecule. As would be understood by the skilled artisan, nine molecules may have a degree of sulfation of three per molecule, while the tenth may have a degree of sulfation of only two. On average, however, the degree of sulfation would be 2.9, which will be understood by the skilled artisan as one of the range of values encompassed by the term “about 3”. MPEP 2173.05(b) provides that “The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph.” Additionally, the MPEP sets forth that “In determining the range encompassed by the term “about”, one must consider the context of the term as it is used in the specification and claims of the application.” (Emphasis added). The context of the term in the instant application is clear to the skilled artisan.

As none of Komai, Tunc, nor Reich, taken alone or in combination with one another, discloses the presently-claimed invention, Applicants submit that the combination of references does not render the pending claims obvious. The combination of references does not provide the skilled artisan with any suggestion or motivation to arrive at the claimed invention, and therefore, the combination of references provides no reasonable expectation of success in

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arriving at the claimed invention. Applicants respectfully request withdrawal of the rejection of claims 9, 10, 17, 19 and 20 under 35 U.S.C. § 103(a).

Conclusion

Applicants respectfully submit that the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 963-5809 to clarify any unresolved issues raised by this response.

The Director is hereby authorized to charge/credit Deposit Account No. **50-0310** (Billing No. 101713-5025) for any other required fees, deficiencies or overpayments in connection with this Response.

Respectfully submitted,

MICHAEL WILLIAM GRADY ET AL.

Date: July 2, 2010

By: /Thomas M. Sossong Jr./

Thomas M. Sossong, Jr., Ph.D.
Registration No. **48,463**
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: (215) 963-5809
Facsimile: (215) 963-5001
E-Mail: tsossong@morganlewis.com